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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,416	07/27/2001	Yukio Yamori	SAEGU85.001A	1599

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EXAMINER

ZUCKER, PAUL A

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 01/17/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/890,416	Applicant(s) YAMORI ET AL.	
	Examiner Paul A. Zucker	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☒ Claim(s) 1,9,12 and 18 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>4</u> . | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Specification

1. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.
2. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Claim Objections

3. Claims 1, 9, 12 and 18 are objected to because of the following informalities: Claims 1, 9, 12 and 18 contain several periods ".". A proper claim should contain only a single period as the final character. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1 -19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1, 9, 12 and 18 recite limitations that are contained within square brackets "[...]" and parentheses "(...)". Enclosing limitations within square brackets or parentheses renders claims 1, 9, 12 and 18, and therefore their dependents, indefinite because it is unclear whether the

limitation(s) contained within square brackets or parentheses are part of the claimed invention.

5. Claims 11 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The independent claims 11 and 19 recite the limitation "formula (I)" but fail to define formula (I). This renders claims 11 and 19 indefinite.
6. Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 15 recites the limitation "climacteric and post-climacteric diseases". It is unclear from this recitation whether applicant intends to limit treatment to only those patients having hypertension and its sequale as a direct result of climacteric changes meaning only menopausal and postmenopausal women. Further, the word "climacteric" has the more general meaning "critical period of life" which is a much broader limitation than the medical definition implied. Claim 15 is thus indefinite and clarification in this matter is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mizutani et al (Biochemical and Biophysical research Communications 1998, 253, pages 859-863) and further in view of Caspar et al (WO 00/38620-A2 07-2000) and further in view of Tortora et al (WO 00/64282-A1 11-2000). Mizutani teaches (Page 859, left column, first two sentences after abstract) that osteoporosis associated with estrogen deficiency after menopause is the most common cause of age related bone loss. Mizutani further discloses (Page 860, FIG.2, bottom right) the effect on ALP (Alkaline Phosphatase) activity of treatment of osteoblastic (bone forming) MC3T3-E1 cells with resveratrol (3, 4',5-trihydroxystilbene, corresponding to instant formula (I)). Mizutani further discloses (Page 859, bottom right, last sentence) pharmaceutical compositions comprising 0.1% BSA, vehicle and/or varying amounts of resveratrol. Mizutani further specifically teaches (Page 862, left column, last sentence) using resveratrol for the treatment of osteoporosis. Mizutani is silent with respect to treatment of periodontal disease (alveolar bone loss) and use of resveratrol in foods and in conjunction with vitamins. Caspar teaches (Page 2, line 12 – page 3, line 3) the use of resveratrol for the treatment of periodontal disease. Caspar further discloses (Page 5, line 3-page 8, line 9) pharmaceutical compositions comprising resveratrol. Caspar is silent with respect to employing resveratrol in food compositions and in conjunction with vitamins. Tortora, however, teaches (Page 2, lines 13-17) the use of resveratrol in functional food product compositions. Tortora also discloses (Page 6, lines 2-3) functional food compositions containing vitamin D3 along with resveratrol. Thus it would have been obvious for

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one of ordinary skill in the art to have performed the instant invention at the time applicant asserts it was made. The motivation would have been to incorporate the bone loss treatment disclosed by Mizutani along with the teachings of Tortora to turn compositions for the treatment of menopausal and alveolar bone loss into food products that would present a more attractive form of administration of the compositions and would lead to better patient compliance. The expectation for success would have been high since all limitations of the invention are taught by the references and all are directed to use of resveratrol.

8. Claims 12-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mizutani et al (Biochemical and Biophysical research Communications 1998, 253, pages 859-863) and further in view of Toppo et al (US 6,048,903 04-2000) and further in view of Tortora et al (WO 00/64282-A1 11-2000). Mizutani teaches (Page 859, right column, lines 10-13) that resveratrol (3, 4',5-trihydroxystilbene, corresponding to instant formula (I)) is derived from grape cultivars (plants of the vitaceae family). Mizutani further discloses (Page 859, right column, lines 13-19) that resveratrol inhibits oxidation of low density lipoprotein, preventing atherosclerotic changes as well as exhibiting a vasorelaxing activity in the isolated aorta of a rat, and is presumably, therefore, useful for the treatment of hypertension. Mizutani is silent with regard to pharmaceutical compositions containing resveratrol for treatment of atherosclerosis and hypertension. Toppo, however, teaches (Column 1, lines 25-31) the link between hypercholesterolemia and hypertension and the effect that resveratrol, from grape skins, has on HDL/LDL levels. Toppo further teaches

(Column 1, lines 49-56) pharmaceutical compositions and forms of oral and transdermal administration as well. Toppo is silent with respect to employing resveratrol in food compositions. Tortora, however, discloses (Page 2, lines 13-17 and Page 5, lines 3-9 and lines 17-18) the use of resveratrol in functional food product compositions. Thus it would have been obvious for one of ordinary skill in the art to have performed the instant invention at the time applicant asserts it was made. The motivation would have been to incorporate resveratrol for the treatment of vascular diseases as disclosed and taught by Mitzutani and Toppo along with the teachings of Tortora to turn compositions for the treatment of atherosclerosis and hypertension into food products that would present a more attractive form of administration of the compositions and would lead to better patient compliance. The expectation for success would have been high since all limitations of the invention are taught by the references and all are directed to use of resveratrol.

Conclusion

9. Claims 1-19 are outstanding. Claims 1-19 are rejected. Claims 1, 9, 12 and 18 are objected to.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul A. Zucker whose telephone number is 703-306-0512. The examiner can normally be reached on Monday-Friday 7:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Geist can be reached on 703-308-1701. The fax phone numbers

for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

PAZ
January 15, 2002



GARY GEIST
SUPERVISORY PATENT EXAMINER
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